

440. Misbranding of Cascarin Compound Tablets. U. S. v. 573 Bottles of S. C. Tablets Cascarin Compound Dr. Hinkle No. 3. Default decree of condemnation and destruction. (F. D. C. No. 3638. Sample No. 32634-E.)

On January 9, 1941, the United States attorney for the District of Arizona filed a libel against 573 bottles of the above-named product at Phoenix, Ariz., alleging that the article had been shipped by the Boyce Pharmacal Co. from Los Angeles, Calif., on or about July 10, 1940; and charging that it was misbranded.

Analysis of a sample showed that the tablets each contained alkaloidal material including strychnine sulfate (approximately 0.024 grain), podophyllin (approximately $\frac{1}{8}$ grain); aloin ($\frac{1}{4}$ grain), and an emodin-bearing drug such as cascara sagrada.

The article was alleged to be misbranded in that the label failed to bear adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health or against unsafe dosage or duration of administration in such manner and form as are necessary for the protection of users, since it did not inform the purchaser that the tablets should not be taken when symptoms of appendicitis are present and that its use by children and elderly persons is particularly dangerous, and did not warn against frequent or continued use of the article when such use is capable of causing dependence upon laxatives to move the bowels. It was alleged to be misbranded further (1) in that the designation "Cascarin Compound," appearing on the label, was false and misleading since it suggested that the essential ingredient in the preparation was derived from some species of cascara when in fact its principal active ingredients were aloin, podophyllin, and strychnine; (2) in that the designation "Dr. Hinkle No. 3," appearing on the label, was false and misleading since it created the impression that the article had the essential composition described in the National Formulary for Hinkle's pills when in fact its composition differed therefrom, particularly in that it contained strychnine sulfate, which is not an ingredient of Hinkle's pills; and (3) in that the label failed to bear the common or usual name of each of its active ingredients since the coined word "Cascarin," appearing on the label in the list of ingredients, was not the common or usual name of any drug.

On February 10, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

441. Misbranding of Crawford's Sa-Lax and Crawford's Formula 53 with Vitamin E. U. S. v. 9 Bottles and 4 Bottles of Crawford's Formula 53 with Vitamin E and 50 Tins of Crawford's Sa-Lax. Default decree of condemnation and destruction. (F. D. C. Nos. 3556, 3558. Sample Nos. 32615-E, 32622-E.)

The label of Crawford's Sa-Lax failed to bear adequate directions and warning statements; and the labeling of both products bore false and misleading therapeutic claims.

On January 6, 1941, the United States attorney for the District of Arizona filed a libel against the above-named products at Tucson, Ariz., alleging that Crawford's Formula 53 had been transported on or about July 18, 1940, by Walter Bopp from Eagle Rock, Calif., and that Crawford's Sa-Lax had been transported on or about July 26, 1940, by Crawford Foods, Inc., from Los Angeles, Calif.; and charging that they were misbranded.

Analyses of samples of the articles showed that Crawford's Sa-Lax Tablets contained the laxative drugs rhubarb root and senna leaf together with Irish moss, okra, and leafy plant materials such as parsley; and that Crawford's Formula 53 Tablets contained plant materials, largely alfalfa (lucerne) leaf and stem tissues, with smaller proportions of other plant materials including tomato seed, anise, fennel, Cayenne pepper (capsicum), celery seed, a leafy material such as parsley, and yeast.

Crawford's Sa-Lax was alleged to be misbranded (1) in that its package failed to bear adequate directions for use since the directions on the bottle label, "The dosage of Crawford's Sa-Lax must be determined by the severity of the case. The adult dosage suggested is two tablets upon retiring, to be increased to one tablet four times per day, with meals and upon retiring in the more severe cases. Children in proportion to age," were not suitable nor appropriate directions for the use of a laxative preparation of the composition of this one and therefore were not adequate; and (2) in that its labeling failed to bear adequate warnings against use in certain pathological conditions or methods or duration of administration in such manner and form as are necessary for the protection of users since its label failed to inform the purchaser that it would be dangerous if